104TH CONGRESS
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H. R. 1022

IN THE SENATE OF THE UNITED STATES

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AN ACT

To provide regulatory reform and to focus national economic resources on the greatest risks to human health, safety, and the environment through scientifically objective and unbiased risk assessments and through the consideration of costs and benefits in major rules, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Risk Assessment and Cost-Benefit Act of 1995''.

SEC. 2. FINDINGS.

The Congress finds that:

(1) Environmental, health, and safety regulations have led to dramatic improvements in the environment and have significantly reduced human health risk; however, the Federal regulations that have led to these improvements have been more costly and less effective than they could have been; too often, regulatory priorities have not been based upon a realistic consideration of risk, risk reduction opportunities, and costs.

(2) The public and private resources available to address health, safety, and environmental concerns are not unlimited; those resources need to be allocated to address the greatest needs in the most cost-effective manner and so that the incremental costs of regulatory alternatives are reasonably related to the incremental benefits.

(3) To provide more cost-effective and cost-reasonable protection to human health and the environment, regulatory priorities should be based upon realistic consideration of risk; the priority setting process must include scientifically sound, objective, and

unbiased risk assessments, comparative risk analysis, and risk management choices that are grounded in cost-benefit principles.

(4) Risk assessment has proven to be a useful decision making tool; however, improvements are needed in both the quality of assessments and the characterization and communication of findings; scientific and other data must be better collected, organized, and evaluated; most importantly, the critical information resulting from a risk assessment must be effectively communicated in an objective and unbiased manner to decision makers, and from decision makers to the public.

(5) The public stake holders must be fully involved in the risk-decision making process. They have the right-to-know about the risks addressed by regulation, the amount of risk to be reduced, the quality of the science used to support decisions, and the cost of implementing and complying with regulations. This knowledge will allow for public scrutiny and promote quality, integrity, and responsiveness of agency decisions.

(6) Although risk assessment is one important method to improve regulatory decision-making, other approaches to secure prompt relief from the burden

of unnecessary and overly complex regulations will also be necessary.

SEC. 3. COVERAGE OF ACT.

This Act does not apply to any of the following:

(1) A situation that the head of an affected Federal agency determines to be an emergency. In such circumstance, the head of the agency shall comply with the provisions of this Act within as reasonable a time as is practical.

(2) Activities necessary to maintain military readiness.

(3) Any individual food, drug, or other product label, or to any risk characterization appearing on any such label, if the individual product label is required by law to be approved by a Federal department or agency prior to use.

(4) Approval of State programs or plans by Federal agencies.

SEC. 4. UNFUNDED MANDATES.

Nothing in this Act itself shall, without Federal funding and further Federal agency action, create any new obligation or burden on any State or local government or otherwise impose any financial burden on any State or local government in the absence of Federal funding, except with respect to routine information requests.

SEC. 5. DEFINITIONS.

For purposes of this Act:

(1) COSTS.—The term ''costs'' includes the direct and indirect costs to the United States Government, to State, local, and tribal governments, and to the private sector, wage earners, consumers, and the economy, of implementing and complying with a rule or alternative strategy.

(2) BENEFIT.—The term ''benefit'' means the reasonably identifiable significant health, safety, environmental, social and economic benefits that are expected to result directly or indirectly from implementation of a rule or alternative strategy.

(3) MAJOR RULE.—The term ''major rule'' means any regulation that is likely to result in an annual increase in costs of $25,000,000 or more. Such term does not include any regulation or other action taken by an agency to authorize or approve any individual substance or product.

(4) PROGRAM DESIGNED TO PROTECT HUMAN HEALTH.—The term ''program designed to protect human health'' does not include regulatory programs concerning health insurance, health provider services, or health care diagnostic services.

(5) EMERGENCY.—As used in this Act, the term ''emergency'' means a situation that is imme-

diately impending and extraordinary in nature, demanding attention due to a condition, circumstance, or practice reasonably expected to cause death, serious illness, or severe injury to humans, or substantial endangerment to private property or the environment if no action is taken.

SEC. 6. AVAILABILITY OF INFORMATION AMONG FEDERAL AGENCIES.

Covered Federal agencies shall make existing databases and information developed under this Act available to other Federal agencies, subject to applicable confidentiality requirements, for the purpose of meeting the requirements of this Act. Within 15 months after the date of enactment of this Act, the President shall issue guidelines for Federal agencies to comply with this section.

TITLE I—RISK ASSESSMENT AND COMMUNICATION

SEC. 101. SHORT TITLE.

This title may be cited as the ''Risk Assessment and Communication Act of 1995''.

SEC. 102. PURPOSES.

The purposes of this title are—

(1) to present the public and executive branch with the most scientifically objective and unbiased information concerning the nature and magnitude of

health, safety, and environmental risks in order to provide for sound regulatory decisions and public education;

(2) to provide for full consideration and discussion of relevant data and potential methodologies;

(3) to require explanation of significant choices in the risk assessment process which will allow for better peer review and public understanding; and

(4) to improve consistency within the executive branch in preparing risk assessments and risk characterizations.

SEC. 103. EFFECTIVE DATE; APPLICABILITY; SAVINGS PROVISIONS.

(a) EFFECTIVE DATE.—Except as otherwise specifically provided in this title, the provisions of this title shall take effect 18 months after the date of enactment of this title.

(b) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (3), this title applies to all significant risk assessment documents and significant risk characterization documents, as defined in paragraph (2).

(2) SIGNIFICANT RISK ASSESSMENT DOCUMENT OR SIGNIFICANT RISK CHARACTERIZATION DOCUMENT.—(A) As used in this title, the terms ''signifi-

cant risk assessment document'' and ''significant risk characterization document'' include, at a minimum, risk assessment documents or risk characterization documents prepared by or on behalf of a covered Federal agency in the implementation of a regulatory program designed to protect human health, safety, or the environment, used as a basis for one of the items referred to in subparagraph (B), and—

(i) included by the agency in that item; or

(ii) inserted by the agency in the administrative record for that item.

(B) The items referred to in subparagraph (A) are the following:

(i) Any proposed or final major rule, including any analysis or certification under title II, promulgated as part of any Federal regulatory program designed to protect human health, safety, or the environment.

(ii) Any proposed or final environmental clean-up plan for a facility or Federal guidelines for the issuance of any such plan. As used in this clause, the term ''environmental clean-up'' means a corrective action under the Solid Waste Disposal Act, a removal or remedial action under the Comprehensive Environmental

Response, Compensation, and Liability Act of 1980, and any other environmental restoration and waste management carried out by or on behalf of a covered Federal agency with respect to any substance other than municipal waste.

(iii) Any proposed or final permit condition placing a restriction on facility siting or operation under Federal laws administered by the Environmental Protection Agency or the Department of the Interior. Nothing in this section (iii) shall apply to the requirements of section 404 of the Clean Water Act.

(iv) Any report to Congress.

(v) Any regulatory action to place a substance on any official list of carcinogens or toxic or hazardous substances or to place a new health effects value on such list, including the Integrated Risk Information System Database maintained by the Environmental Protection Agency.

(vi) Any guidance, including protocols of general applicability, establishing policy regarding risk assessment or risk characterization.

(C) The terms ''significant risk assessment document'' and ''significant risk characterization document'' shall also include the following:

(i) Any such risk assessment and risk characterization documents provided by a covered Federal agency to the public and which are likely to result in an annual increase in costs of $25,000,000 or more.

(ii) Environmental restoration and waste management carried out by or on behalf of the Department of Defense with respect to any substance other than municipal waste.

(D) Within 15 months after the date of the enactment of this Act, each covered Federal agency administering a regulatory program designed to protect human health, safety, or the environment shall promulgate a rule establishing those additional categories, if any, of risk assessment and risk characterization documents prepared by or on behalf of the covered Federal agency that the agency will consider significant risk assessment documents or significant risk characterization documents for purposes of this title. In establishing such categories, the head of the agency shall consider each of the following:

(i) The benefits of consistent compliance by documents of the covered Federal agency in the categories.

(ii) The administrative burdens of including documents in the categories.

(iii) The need to make expeditious administrative decisions regarding documents in the categories.

(iv) The possible use of a risk assessment or risk characterization in any compilation of risk hazards or health or environmental effects prepared by an agency and commonly made available to, or used by, any Federal, State, or local government agency.

(v) Such other factors as may be appropriate.

(E)(i) Not later than 18 months after the date of the enactment of this Act, the President, acting through the Director of the Office of Management and Budget, shall determine whether any other Federal agencies should be considered covered Federal agencies for purposes of this title. Such determination, with respect to a particular Federal agency, shall be based on the impact of risk assessment documents and risk characterization documents on—

(I) regulatory programs administered by that agency; and

(II) the communication of risk information by that agency to the public.

The effective date of such a determination shall be no later than 6 months after the date of the determination.

(ii) Not later than 15 months after the President, acting through the Director of the Office of Management and Budget, determines pursuant to clause (i) that a Federal agency should be considered a covered Federal agency for purposes of this title, the head of that agency shall promulgate a rule pursuant to subparagraph (D) to establish additional categories of risk assessment and risk characterization documents described in that subparagraph.

(3) EXCEPTIONS.—(A) This title does not apply to risk assessment or risk characterization documents containing risk assessments or risk characterizations performed with respect to the following:

(i) A screening analysis, where appropriately labeled as such, including a screening analysis for purposes of product regulation or premanufacturing notices.

(ii) Any health, safety, or environmental inspections.

(iii) The sale or lease of Federal resources or regulatory activities that directly result in the collection of Federal receipts.

(B) No analysis shall be treated as a screening analysis for purposes of subparagraph (A) if the results of such analysis are used as the basis for imposing restrictions on substances or activities.

(C) The risk assessment principle set forth in section 104(b)(1) need not apply to any risk assessment or risk characterization document described in clause (iii) of paragraph (2)(B). The risk characterization and communication principle set forth in section 105(4) need not apply to any risk assessment or risk characterization document described in clause (v) or (vi) of paragraph (2)(B).

(c) SAVINGS PROVISIONS.—The provisions of this title shall be supplemental to any other provisions of law relating to risk assessments and risk characterizations, except that nothing in this title shall be construed to modify any statutory standard or statutory requirement designed to protect health, safety, or the environment. Nothing in this title shall be interpreted to preclude the consideration of any data or the calculation of any estimate to more

fully describe risk or provide examples of scientific uncertainty or variability. Nothing in this title shall be construed to require the disclosure of any trade secret or other confidential information.

SEC. 104. PRINCIPLES FOR RISK ASSESSMENT.

(a) IN GENERAL.—The head of each covered Federal agency shall apply the principles set forth in subsection (b) in order to assure that significant risk assessment documents and all of their components distinguish scientific findings from other considerations and are, to the extent feasible, scientifically objective, unbiased, and inclusive of all relevant data and rely, to the extent available and practicable, on scientific findings. Discussions or explanations required under this section need not be repeated in each risk assessment document as long as there is a reference to the relevant discussion or explanation in another agency document which is available to the public.

(b) PRINCIPLES.—The principles to be applied are as follows:

(1) When discussing human health risks, a significant risk assessment document shall contain a discussion of both relevant laboratory and relevant epidemiological data of sufficient quality which finds, or fails to find, a correlation between health risks and a potential toxin or activity. Where conflicts

among such data appear to exist, or where animal data is used as a basis to assess human health, the significant risk assessment document shall, to the extent feasible and appropriate, include discussion of possible reconciliation of conflicting information, and as relevant, differences in study designs, comparative physiology, routes of exposure, bioavailability, pharmacokinetics, and any other relevant factor, including the sufficiency of basic data for review. The discussion of possible reconciliation should indicate whether there is a biological basis to assume a resulting harm in humans. Animal data shall be reviewed with regard to its relevancy to humans.

(2) Where a significant risk assessment document involves selection of any significant assumption, inference, or model, the document shall, to the extent feasible—

(A) present a representative list and explanation of plausible and alternative assumptions, inferences, or models;

(B) explain the basis for any choices;

(C) identify any policy or value judgments;

(D) fully describe any model used in the risk assessment and make explicit the assumptions incorporated in the model; and

(E) indicate the extent to which any significant model has been validated by, or conflicts with, empirical data.

SEC. 105. PRINCIPLES FOR RISK CHARACTERIZATION AND COMMUNICATION.

Each significant risk characterization document shall meet each of the following requirements:

(1) ESTIMATES OF RISK.—The risk characterization shall describe the populations or natural resources which are the subject of the risk characterization. If a numerical estimate of risk is provided, the agency shall, to the extent feasible, provide—

(A) the best estimate or estimates for the specific populations or natural resources which are the subject of the characterization (based on the information available to the Federal agency); and

(B) a statement of the reasonable range of scientific uncertainties.

In addition to such best estimate or estimates, the risk characterization document may present plausible upper-bound or conservative estimates in conjunction with plausible lower bounds estimates. Where appropriate, the risk characterization document may present, in lieu of a single best estimate,

multiple best estimates based on assumptions, inferences, or models which are equally plausible, given current scientific understanding. To the extent practical and appropriate, the document shall provide descriptions of the distribution and probability of risk estimates to reflect differences in exposure variability or sensitivity in populations and attendant uncertainties. Sensitive subpopulations or highly exposed subpopulations include, where relevant and appropriate, children, the elderly, pregnant women, and disabled persons.

(2) EXPOSURE SCENARIOS.—The risk characterization document shall explain the exposure scenarios used in any risk assessment, and, to the extent feasible, provide a statement of the size of the corresponding population at risk and the likelihood of such exposure scenarios.

(3) COMPARISONS.—The document shall contain a statement that places the nature and magnitude of risks to human health, safety, or the environment in context. Such statement shall, to the extent feasible, provide comparisons with estimates of greater, lesser, and substantially equivalent risks that are familiar to and routinely encountered by the general public as well as other risks, and, where ap-

propriate and meaningful, comparisons of those risks with other similar risks regulated by the Federal agency resulting from comparable activities and exposure pathways. Such comparisons should consider relevant distinctions among risks, such as the voluntary or involuntary nature of risks and the preventability or nonpreventability of risks.

(4) SUBSTITUTION RISKS.—Each significant risk assessment or risk characterization document shall include a statement of any significant substitution risks to human health, where information on such risks has been provided to the agency.

(5) SUMMARIES OF OTHER RISK ESTIMATES.—If—

(A) a commenter provides a covered Federal agency with a relevant risk assessment document or a risk characterization document, and a summary thereof, during a public comment provided by the agency for a significant risk assessment document or a significant risk characterization document, or, where no comment period is provided but a commenter provides the covered Federal agency with the relevant risk assessment document or risk characterization

document, and a summary thereof, in a timely fashion, and

(B) the risk assessment document or risk characterization document is consistent with the principles and the guidance provided under this title,

the agency shall, to the extent feasible, present such summary in connection with the presentation of the agency's significant risk assessment document or significant risk characterization document. Nothing in this paragraph shall be construed to limit the inclusion of any comments or material supplied by any person to the administrative record of any proceeding.

A document may satisfy the requirements of paragraph (3), (4) or (5) by reference to information or material otherwise available to the public if the document provides a brief summary of such information or material.

SEC. 106. RECOMMENDATIONS OR CLASSIFICATIONS BY A NON-UNITED STATES-BASED ENTITY.

No covered Federal agency shall automatically incorporate or adopt any recommendation or classification made by a non-United States-based entity concerning the health effects value of a substance without an opportunity for notice and comment, and any risk assessment docu-

ment or risk characterization document adopted by a covered Federal agency on the basis of such a recommendation or classification shall comply with the provisions of this title. For the purposes of this section, the term ''non-United States-based entity'' means—

(1) any foreign government and its agencies;

(2) the United Nations or any of its subsidiary organizations;

(3) any other international governmental body or international standards-making organization; or

(4) any other organization or private entity without a place of business located in the United States or its territories.

SEC. 107. GUIDELINES AND REPORT.

(a) GUIDELINES.—Within 15 months after the date of enactment of this title, the President shall issue guidelines for Federal agencies consistent with the risk assessment and characterization principles set forth in sections 104 and 105 and shall provide a format for summarizing risk assessment results. In addition, such guidelines shall include guidance on at least the following subjects: criteria for scaling animal studies to assess risks to human health; use of different types of dose-response models; thresholds; definitions, use, and interpretations of the maximum tolerated dose; weighting of evidence with respect to extrapo-

lating human health risks from sensitive species; evaluation of benign tumors, and evaluation of different human health endpoints.

(b) REPORT.—Within 3 years after the enactment of this title, each covered Federal agency shall provide a report to the Congress evaluating the categories of policy and value judgments identified under subparagraph (C) of section 104(b)(2).

(c) PUBLIC COMMENT AND CONSULTATION.—The guidelines and report under this section, shall be developed after notice and opportunity for public comment, and after consultation with representatives of appropriate State, local, and tribal governments, and such other departments and agencies, offices, organizations, or persons as may be advisable.

(d) REVIEW.—The President shall review and, where appropriate, revise the guidelines published under this section at least every 4 years.

SEC. 108. RESEARCH AND TRAINING IN RISK ASSESSMENT.

(a) EVALUATION.—The head of each covered agency shall regularly and systematically evaluate risk assessment research and training needs of the agency, including, where relevant and appropriate, the following:

(1) Research to reduce generic data gaps, to address modelling needs (including improved model

sensitivity), and to validate default options, particularly those common to multiple risk assessments.

(2) Research leading to improvement of methods to quantify and communicate uncertainty and variability among individuals, species, populations, and, in the case of ecological risk assessment, ecological communities.

(3) Emerging and future areas of research, including research on comparative risk analysis, exposure to multiple chemicals and other stressors, noncancer endpoints, biological markers of exposure and effect, mechanisms of action in both mammalian and nonmammalian species, dynamics and probabilities of physiological and ecosystem exposures, and prediction of ecosystem-level responses.

(4) Long-term needs to adequately train individuals in risk assessment and risk assessment application. Evaluations under this paragraph shall include an estimate of the resources needed to provide necessary training.

(b) STRATEGY AND ACTIONS TO MEET IDENTIFIED NEEDS.—The head of each covered agency shall develop a strategy and schedule for carrying out research and training to meet the needs identified in subsection (a).

(c) REPORT.—Not later than 6 months after the date of the enactment of this Act, the head of each covered agency shall submit to the Congress a report on the evaluations conducted under subsection (a) and the strategy and schedule developed under subsection (b). The head of each covered agency shall report to the Congress periodically on the evaluations, strategy, and schedule.

SEC. 109. STUDY OF COMPARATIVE RISK ANALYSIS.

(a) IN GENERAL.—(1) The Director of the Office of Management and Budget, in consultation with the Office of Science and Technology Policy, shall conduct, or provide for the conduct of, a study using comparative risk analysis to rank health, safety, and environmental risks and to provide a common basis for evaluating strategies for reducing or preventing those risks. The goal of the study shall be to improve methods of comparative risk analysis.

(2) Not later than 90 days after the date of the enactment of this Act, the Director, in collaboration with the heads of appropriate Federal agencies, shall enter into a contract with the National Research Council to provide technical guidance on approaches to using comparative risk analysis and other considerations in setting health, safety, and environmental risk reduction priorities.

(b) SCOPE OF STUDY.—The study shall have sufficient scope and breadth to evaluate comparative risk analysis and to test approaches for improving comparative risk analysis and its use in setting priorities for health, safety, and environmental risk reduction. The study shall compare and evaluate a range of diverse health, safety, and environmental risks.

(c) STUDY PARTICIPANTS.—In conducting the study, the Director shall provide for the participation of a range of individuals with varying backgrounds and expertise, both technical and nontechnical, comprising broad representation of the public and private sectors.

(d) DURATION.—The study shall begin within 180 days after the date of the enactment of this Act and terminate within 2 years after the date on which it began.

(e) RECOMMENDATIONS FOR IMPROVING COMPARATIVE RISK ANALYSIS AND ITS USE.—Not later than 90 days after the termination of the study, the Director shall submit to the Congress the report of the National Research Council with recommendations regarding the use of comparative risk analysis and ways to improve the use of comparative risk analysis for decision-making in appropriate Federal agencies.

SEC. 110. DEFINITIONS.

For purposes of this title:

(1) RISK ASSESSMENT DOCUMENT.—The term ''risk assessment document'' means a document containing the explanation of how hazards associated with a substance, activity, or condition have been identified, quantified, and assessed. The term also includes a written statement accepting the findings of any such document.

(2) RISK CHARACTERIZATION DOCUMENT.—The term ''risk characterization document'' means a document quantifying or describing the degree of toxicity, exposure, or other risk posed by hazards associated with a substance, activity, or condition to which individuals, populations, or resources are exposed. The term also includes a written statement accepting the findings of any such document.

(3) BEST ESTIMATE.—The term ''best estimate'' means a scientifically appropriate estimate which is based, to the extent feasible, on one of the following:

(A) Central estimates of risk using the most plausible assumptions.

(B) An approach which combines multiple estimates based on different scenarios and weighs the probability of each scenario.

(C) Any other methodology designed to provide the most unbiased representation of the most plausible level of risk, given the current scientific information available to the Federal agency concerned.

(4) SUBSTITUTION RISK.—The term ''substitution risk'' means a potential risk to human health, safety, or the environment from a regulatory alternative designed to decrease other risks.

(5) COVERED FEDERAL AGENCY.—The term ''covered Federal agency'' means each of the following:

(A) The Environmental Protection Agency.

(B) The Occupational Safety and Health Administration.

(C) The Department of Transportation (including the National Highway Transportation Safety Administration).

(D) The Food and Drug Administration.

(E) The Department of Energy.

(F) The Department of the Interior.

(G) The Department of Agriculture.

(H) The Consumer Product Safety Commission.

(I) The National Oceanic and Atmospheric Administration

(J) The United States Army Corps of Engineers.

(K) The Mine Safety and Health Administration.

(L) The Nuclear Regulatory Commission.

(M) Any other Federal agency considered a covered Federal agency pursuant to section 103(b)(2)(E).

(6) FEDERAL AGENCY.—The term ''Federal agency'' means an executive department, military department, or independent establishment as defined in part I of title 5 of the United States Code, except that such term also includes the Office of Technology Assessment.

(7) DOCUMENT.—The term ''document'' includes material stored in electronic or digital form.

TITLE II—ANALYSIS OF RISK REDUCTION BENEFITS AND COSTS

SEC. 201. ANALYSIS OF RISK REDUCTION BENEFITS AND COSTS.

(a) IN GENERAL.—The President shall require each Federal agency to prepare the following for each major

rule within a program designed to protect human health, safety, or the environment that is proposed or promulgated by the agency after the date of enactment of this Act:

(1) An identification of reasonable alternative strategies, including strategies that—

(A) require no government action;

(B) will accommodate differences among geographic regions and among persons with different levels of resources with which to comply; and

(C) employ performance or other market-based mechanisms that permit the greatest flexibility in achieving the identified benefits of the rule.

The agency shall consider reasonable alternative strategies proposed during the comment period.

(2) An analysis of the incremental costs and incremental risk reduction or other benefits associated with each alternative strategy identified or considered by the agency. Costs and benefits shall be quantified to the extent feasible and appropriate and may otherwise be qualitatively described.

(3) A statement that places in context the nature and magnitude of the risks to be addressed and

the residual risks likely to remain for each alternative strategy identified or considered by the agency. Such statement shall, to the extent feasible, provide comparisons with estimates of greater, lesser, and substantially equivalent risks that are familiar to and routinely encountered by the general public as well as other risks, and, where appropriate and meaningful, comparisons of those risks with other similar risks regulated by the Federal agency resulting from comparable activities and exposure pathways. Such comparisons should consider relevant distinctions among risks, such as the voluntary or involuntary nature of risks and the preventability or nonpreventability of risks.

(4) For each final rule, an analysis of whether the identified benefits of the rule are likely to exceed the identified costs of the rule.

(5) An analysis of the effect of the rule—

(A) on small businesses with fewer than 100 employees;

(B) on net employment; and

(C) to the extent practicable, on the cumulative financial burden of compliance with the rule and other existing regulations on persons producing products.

(b) PUBLICATION.—For each major rule referred to in subsection (a) each Federal agency shall publish in a clear and concise manner in the Federal Register along with the proposed and final regulation, or otherwise make publicly available, the information required to be prepared under subsection (a).

SEC. 202. DECISION CRITERIA.

(a) IN GENERAL.—No final rule subject to the provisions of this title shall be promulgated unless the agency certifies the following:

(1) That the analyses under section 201 are based on objective and unbiased scientific and economic evaluations of all significant and relevant information and risk assessments provided to the agency by interested parties relating to the costs, risks, and risk reduction and other benefits addressed by the rule.

(2) That the incremental risk reduction or other benefits of any strategy chosen will be likely to justify, and be reasonably related to, the incremental costs incurred by State, local, and tribal governments, the Federal Government, and other public and private entities.

(3) That other alternative strategies identified or considered by the agency were found either (A)

to be less cost-effective at achieving a substantially equivalent reduction in risk, or (B) to provide less flexibility to State, local, or tribal governments or regulated entities in achieving the otherwise applicable objectives of the regulation, along with a brief explanation of why alternative strategies that were identified or considered by the agency were found to be less cost-effective or less flexible.

(b) EFFECT OF DECISION CRITERIA.—

(1) IN GENERAL.—Notwithstanding any other provision of Federal law, the decision criteria of subsection (a) shall supplement and, to the extent there is a conflict, supersede the decision criteria for rulemaking otherwise applicable under the statute pursuant to which the rule is promulgated.

(2) SUBSTANTIAL EVIDENCE.—Notwithstanding any other provision of Federal law, no major rule shall be promulgated by any Federal agency pertaining to the protection of health, safety, or the environment unless the requirements of section 201 and subsection (a) are met and the certifications required therein are supported by substantial evidence of the rulemaking record.

(c) PUBLICATION.—The agency shall publish in the Federal Register, along with the final regulation, the certifications required by subsection (a).

(d) NOTICE.—Where the agency finds a conflict between the decision criteria of this section and the decision criteria of an otherwise applicable statute, the agency shall so notify the Congress in writing.

SEC. 203. OFFICE OF MANAGEMENT AND THE BUDGET GUIDANCE.

The Office of Management and Budget shall issue guidance consistent with this title—

(1) to assist the agencies, the public, and the regulated community in the implementation of this title, including any new requirements or procedures needed to supplement prior agency practice; and

(2) governing the development and preparation of analyses of risk reduction benefits and costs.

SEC. 204. ENVIRONMENTAL CLEAN-UP.

For purposes of this title, any determination by a Federal agency to approve or reject any proposed or final environmental clean-up plan for a facility the costs of which are likely to exceed $5,000,000 shall be treated as major rule subject to the provisions of this title (other than the provisions of section 201(a)(5)). As used in this section, the term ''environmental clean-up'' means a cor-

rective action under the Solid Waste Disposal Act, a remedial action under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, and any other environmental restoration and waste management carried out by or on behalf of a Federal agency with respect to any substance other than municipal waste.

TITLE III—PEER REVIEW

SEC. 301. PEER REVIEW PROGRAM.

(a) ESTABLISHMENT.—For regulatory programs designed to protect human health, safety, or the environment, the head of each Federal agency shall develop a systematic program for independent and external peer review required by subsection (b). Such program shall be applicable across the agency and—

(1) shall provide for the creation of peer review panels consisting of experts and shall be broadly representative and balanced and to the extent relevant and appropriate, may include representatives of State, local, and tribal governments, small businesses, other representatives of industry, universities, agriculture, labor, consumers, conservation organizations, or other public interest groups and organizations;

(2) may provide for differing levels of peer review and differing numbers of experts on peer review

panels, depending on the significance or the complexity of the problems or the need for expeditiousness;

(3) shall not exclude peer reviewers with substantial and relevant expertise merely because they represent entities that may have a potential interest in the outcome, provided that interest is fully disclosed to the agency and in the case of a regulatory decision affecting a single entity, no peer reviewer representing such entity may be included on the panel;

(4) may provide specific and reasonable deadlines for peer review panels to submit reports under subsection (c); and

(5) shall provide adequate protections for confidential business information and trade secrets, including requiring peer reviewers to enter into confidentiality agreements.

(b) REQUIREMENT FOR PEER REVIEW.—In connection with any rule that is likely to result in an annual increase in costs of $100,000,000 or more (other than any rule or other action taken by an agency to authorize or approve any individual substance or product), each Federal agency shall provide for peer review in accordance with this section of any risk assessment or cost analysis

which forms the basis for such rule or of any analysis under section 201(a). In addition, the Director of the Office of Management and Budget may order that peer review be provided for any major risk assessment or cost assessment that is likely to have a significant impact on public policy decisions.

(c) CONTENTS.—Each peer review under this section shall include a report to the Federal agency concerned with respect to the scientific and economic merit of data and methods used for the assessments and analyses.

(d) RESPONSE TO PEER REVIEW.—The head of the Federal agency shall provide a written response to all significant peer review comments.

(e) AVAILABILITY TO PUBLIC.—All peer review comments or conclusions and the agency's responses shall be made available to the public and shall be made part of the administrative record.

(f) PREVIOUSLY REVIEWED DATA AND ANALYSIS.—No peer review shall be required under this section for any data or method which has been previously subjected to peer review or for any component of any analysis or assessment previously subjected to peer review.

(g) NATIONAL PANELS.—The President shall appoint National Peer Review Panels to annually review the risk assessment and cost assessment practices of each Federal

agency for programs designed to protect human health, safety, or the environment. The Panel shall submit a report to the Congress no less frequently than annually containing the results of such review.

TITLE IV—JUDICIAL REVIEW

SEC. 401. JUDICIAL REVIEW.

Compliance or noncompliance by a Federal agency with the requirements of this Act shall be reviewable pursuant to the statute granting the agency authority to act or, as applicable, that statute and the Administrative Procedure Act. The court with jurisdiction to review final agency action under the statute granting the agency authority to act shall have jurisdiction to review, at the same time, the agency's compliance with the requirements of this Act. When a significant risk assessment document or risk characterization document subject to title I is part of the administrative record in a final agency action, in addition to any other matters that the court may consider in deciding whether the agency's action was lawful, the court shall consider the agency action unlawful if such significant risk assessment document or significant risk characterization document does not substantially comply with the requirements of sections 104 and 105.

TITLE V—PLAN

SEC. 501. PLAN FOR ASSESSING NEW INFORMATION.

(a) PLAN.—Within 18 months after the date of enactment of this Act, each covered Federal agency (as defined in title I) shall publish a plan to review and, where appropriate revise any significant risk assessment document or significant risk characterization document published prior to the expiration of such 18-month period if, based on information available at the time of such review, the agency head determines that the application of the principles set forth in sections 104 and 105 would be likely to significantly alter the results of the prior risk assessment or risk characterization. The plan shall provide procedures for receiving and considering new information and risk assessments from the public. The plan may set priorities and procedures for review and, where appropriate, revision of such risk assessment documents and risk characterization documents and of health or environmental effects values. The plan may also set priorities and procedures for review, and, where appropriate, revision or repeal of major rules promulgated prior to the expiration of such period. Such priorities and procedures shall be based on the potential to more efficiently focus national economic resources within Federal regulatory programs designed to protect human health, safety, or the environ-

ment on the most important priorities and on such other factors as such Federal agency considers appropriate.

(b) PUBLIC COMMENT AND CONSULTATION.—The plan under this section, shall be developed after notice and opportunity for public comment, and after consultation with representatives of appropriate State, local, and tribal governments, and such other departments and agencies, offices, organizations, or persons as may be advisable.

TITLE VI—PRIORITIES

SEC. 601. PRIORITIES.

(a) IDENTIFICATION OF OPPORTUNITIES.—In order to assist in the public policy and regulation of risks to public health, the President shall identify opportunities to reflect priorities within existing Federal regulatory programs designed to protect human health in a cost-effective and cost-reasonable manner. The President shall identify each of the following:

(1) The likelihood and severity of public health risks addressed by current Federal programs.

(2) The number of individuals affected.

(3) The incremental costs and risk reduction benefits associated with regulatory or other strategies.

(4) The cost-effectiveness of regulatory or other strategies to reduce risks to public health.

(5) Intergovernmental relationships among Federal, State, and local governments among programs designed to protect public health.

(6) Statutory, regulatory, or administrative obstacles to allocating national economic resources based on the most cost-effective, cost-reasonable priorities considering Federal, State, and local programs.

(b) STATE, LOCAL, AND TRIBAL PRIORITIES.—In identifying national priorities, the President shall consider priorities developed and submitted by State, local, and tribal governments.

(c) BIENNIAL REPORTS.—The President shall issue biennial reports to Congress, after notice and opportunity for public comment, to recommend priorities for modifications to, elimination of, or strategies for existing Federal regulatory programs designed to protect public health. Within 6 months after the issuance of the report, the President shall notify the Congress in writing of the recommendations which can be implemented without further legislative changes and the agency shall consider the priorities set forth in the report and priorities developed and submitted by State, local, and tribal governments when

preparing a budget or strategic plan for any such regulatory program.

Passed the House of Representatives February 28, 1995.

Attest: ROBIN H. CARLE,
Clerk.